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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov , or call the Reports Clearance Office on (202) 690-5683. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail within 60 days.

Proposed Project: Institutional Review Board Form – Extension-OMB No. 0990-0279 - Office for Human Research Protections

Abstract: The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form. This form was modified in 2009 to be consistent with IRB registration requirements that were adopted in July 2009 by OHRP and FDA, respectively. Respondents for this information collection are institutions or organizations operating IRBs designated by an institution under an assurance of compliance approved for federalwide use by OHRP under 45 CFR 46.103(a) and that review human subjects research conducted or supported by HHS, or, in the case of FDA's regulation, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
IRB Registration - 0279	6,100	2	1	12,200
	900	2	1	1,800
Total				14,000

Keith A. Tucker

Paperwork Reduction Act Reports Clearance Officer

Office of the Secretary

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